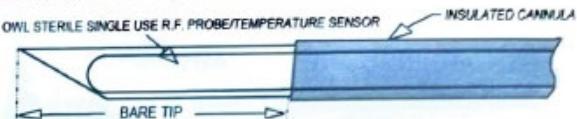


EXHIBIT D

DIROS Trident RF Insulated Cannula (Model DTR) in view of U.S. Patent No. 10,925,664

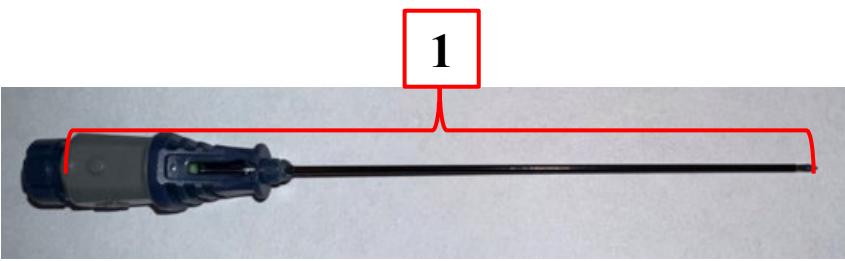
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U.S. Patent No. 10,925,664	Trident RF Insulated Cannula (Model DTR)
A method comprising:	<p>To the extent the preamble is limiting, the Procedure Section of the Diros Instructions For Use (“IFU”) of the DTR is pictured and describes a method of using the DTR. (Exhibit I (Instructions For Use OWL Sterile Single Use Trident™ RF Insulated Cannula, Model DTR, Diros Document 174 at p. 5 (2020)).</p> <p>6.3 Procedure</p> <ol style="list-style-type: none"> 1. Assemble all required equipment for the intended procedure and position the patient as necessary. 2. Attach the Return Path Electrode (GD-Pad). Read and follow the manufacturer's instructions for use of the GD-Pad electrode to determine proper placement. Always use return path electrodes that meet or exceed ANSI/AAMI HF-18 requirements. 3. Inspect the part number of the RF Probe/Temperature Sensor to ensure that it is the correct length to match the length of the Trident™ RF Insulated Cannula. 4. Test the match by removing the stylet from the cannula and slowly inserting the RF Probe/Temperature Sensor into the cannula. Do not use excessive force to avoid damage to the RF Probe. The tip of the RF probe must lie within the bare tip of the RF cannula, see Figure 2. Otherwise the measured temperature will be incorrect. To further verify this, note the position of the handle of the RF Probe, Figure 1 (9) relative to the threaded top section of the Actuator, Figure 1 (4c). Then remove the RF Probe from the RF Cannula, place it parallel to and alongside the cannula and confirm that the tip of the RF Probe is no more than 1 mm short of the end of the RF Cannula bevel, but does not extend beyond it. Reinsert the Stylet into the RF Cannula. 5. Connect the plug of the intermediate cable to an input of the Multi-Lesion Adaptor or to the Probe receptacle on the RF Generator. Maintain access to the probe connection end of the intermediate cable in order to facilitate easy attachment to the RF Probe/Temperature Sensor to it.  <p>OWL STERILE SINGLE USE R.F. PROBE/TEMPERATURE SENSOR SHOULD BE LOCATED AS SHOWN ABOVE</p> <p>Figure 2. Correct position of RF Probe/Temperature Sensor within the Trident™ RF Insulated Cannula. Tines are not shown.</p>

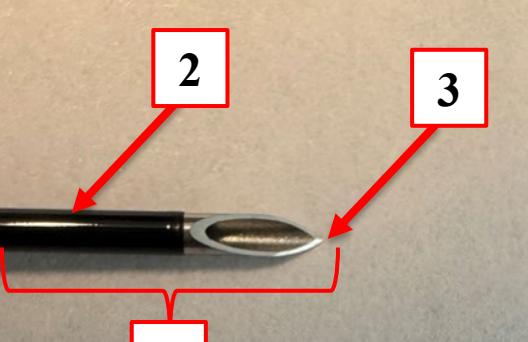
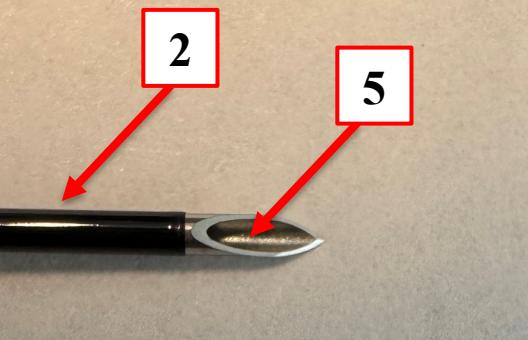
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	<p>6. Re-insert the stylet into the Trident™ RF Insulated Cannula and ensure that the tines are fully withdrawn into it. A distinct click will be heard to indicate full withdrawal. Following superficial anesthesia hold the cannula <i>only</i> by its hub (not by the actuator) and insert it into the patient at a predetermined skin site and, using fluoroscopic guidance, position the active tip at the desired lesion location.</p> <p>7. Once the cannula is properly positioned carefully remove the stylet from the cannula and insert the full length of the RF Probe/Temperature Sensor down the shaft of the Sterile Single Use Trident™ RF Insulated Cannula.</p> <p>8. Plug the probe connector to the probe connection of the intermediate cable. Check if device is reading room temperature before placing it into a patient.</p> <p>9. If proper connection is made, then the RF Generator should read within correct ranges of impedance and body temperature. Otherwise check all connections listed above.</p> <p>10. Apply sensory and/or motor electrical stimulation as indicated by your protocol to verify correct electrode placement. If the results of stimulation are not acceptable and repositioning of the cannula is required, first fully withdraw the tines into the cannula and then reposition. Repeat electrical stimulation as indicated.</p> <p>11. Lesion as necessary. Refer to the RF Generator User's Manual for more information. Upon completion, remove the RF Probe/Temperature Sensor and instill anesthetic and steroid if in accordance with your protocol. When connecting/disconnecting the RF Cannula to the syringe, ensure once again to grasp the cannula only by its hub. Upon completion of the procedure, remove the Trident™ RF Insulated Cannula (with RF Probe/Temperature Sensor still in it if no anesthetic applied).</p> <p>12. Dispose of single use products properly.</p>

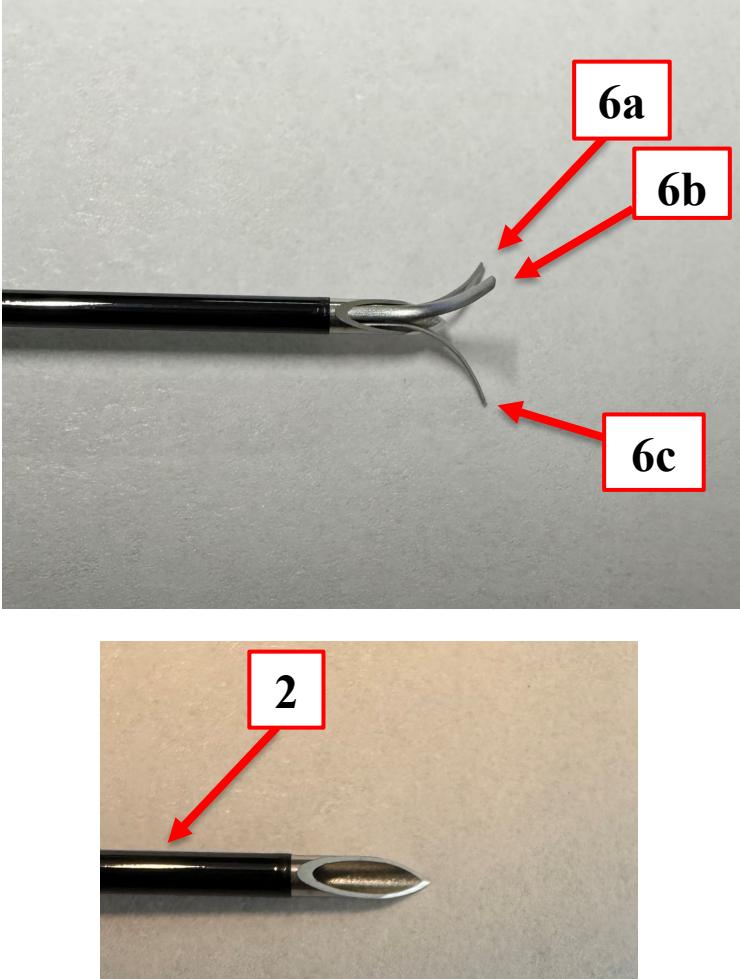
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inserting a needle into a patient, the needle comprising;	<p>The DTR device has a needle [1] that is configured and intended to be inserted into a patient.</p> <p>For example, in Step 6 of the Procedure, the IFU instructs a user to insert the device into the patient “at a predetermined skin site.” (Exhibit I at p. 5).</p>  <p>6. Re-insert the stylet into the Trident™ RF Insulated Cannula and ensure that the tines are fully withdrawn into it. A distinct click will be heard to indicate full withdrawal. Following superficial anesthesia hold the cannula <u>only</u> by its hub (not by the actuator) and <u>insert it into the patient at a predetermined skin site</u>, and, using fluoroscopic guidance, position the active tip at the desired lesion location.</p>
an elongate member;	<p>As shown, the DTR device’s needle has an elongate member [2].</p> 

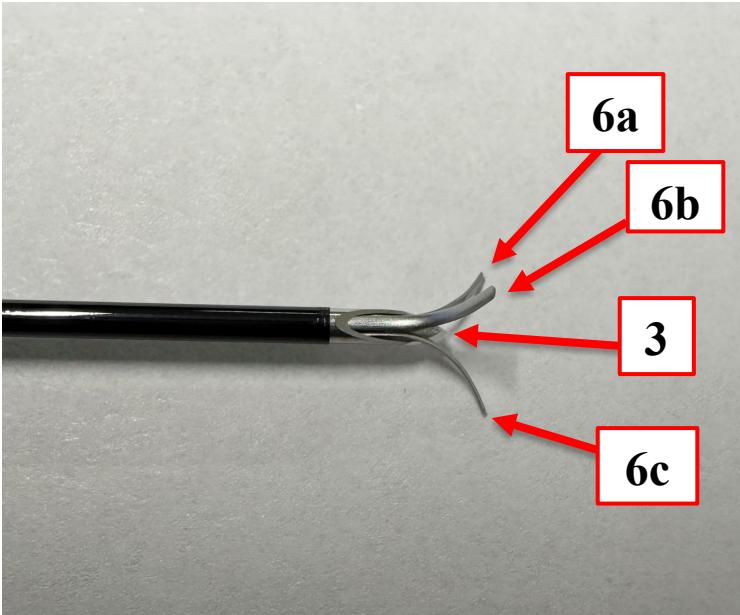
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a piercing tip at a distal end of the elongate member;	<p>As shown, the DTR device's needle has a tip [3], which is fixed to the elongate member [2] at the distal end [4]. The tip [3] is sharp and beveled and thus would be understood to be shaped for the purpose of piercing the tissue of a patient. Moreover, as previously discussed, in Step 6 of the Procedure, the IFU instructs a user to insert the needle into the patient "at a predetermined skin site." (Exhibit I at p. 5).</p>  <p>Annotations:</p> <ul style="list-style-type: none"> 2: Points to the elongate member. 3: Points to the sharp, beveled tip. 4: Points to the distal end where the tip is attached.
a lumen within the elongate member; and	<p>As shown, the DTR's needle has a lumen [5] within the elongate member [2].</p>  <p>Annotations:</p> <ul style="list-style-type: none"> 2: Points to the elongate member. 5: Points to the lumen within the elongate member.

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a filament in a retracted position in which the filament is at least partially disposed within the elongate member;	<p>The DTR's needle comprises filaments [6a-c] which are visible when in the deployed position, as shown in the first image to the right.</p> <p>As shown in the second image to the right, the filaments [6a-c] are not visible because they are at least partially disposed within the elongate member [2].</p> 

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<p>moving the filament to a deployed position within the patient in which at least a distal end of the filament is out of the elongate member and disposed away from the tip;</p>	<p>As described in the DTR IFU, the “[c]annula hub/handle is equipped with a mechanism that allows deployment and retraction of 3 tines [i.e., filaments].” (Exhibit I at p. 1; <i>see also id.</i> at p. 4 (further describing deployment and retraction of filaments)).</p> <p>As shown in the second image at right, the distal ends of the filaments [6a-c] extend beyond and are disposed away from the tip [3] in the deployed position.</p> <p>As described in Step 6 of the Procedure, the DTR’s needle is inserted into the patient “at a predetermined skin site.” (Exhibit I at p. 5). As previously discussed, the needle is inserted using the tip at the distal end of the needle, the tip being sharp and beveled and therefore configured and intended to be inserted into a patient.</p> <p>As later described in Step 10 of the Procedure, “sensory and/or motor electrical stimulation” is then applied to the patient. (Exhibit I at p. 5).</p> <p><i>The Cannula hub/handle is constructed from stainless steel tubing. Cannulae consist of partially insulated shaft, plastic hub/handle and three tines. The hub/handle is equipped with a mechanism that allows deployment and retraction of 3 tines.</i></p>  <p>10. Apply <u>sensory and/or motor electrical stimulation</u> as indicated by your protocol to verify correct electrode placement. <u>If the results of stimulation are not acceptable and repositioning of the cannula is required, first fully withdraw the tines into the cannula and then reposition. Repeat electrical stimulation as indicated.</u></p> <p>...</p>

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	<p>p. 5). In the Important notes following the Procedure, the tines (i.e., filaments) “must be fully deployed before stimulation, otherwise results will be erroneous.” (<i>Id.</i>) Further, Step 10 states, “If the results of stimulation are not acceptable and repositioning of the cannula is required, first fully withdraw the tines [i.e., filaments].” (<i>Id.</i>)</p> <p>Because Step 10 occurs after the tip [3] of the needle is inserted into the patient in Step 6, the method would be understood to require the filaments [6a-c] to be in the deployed position within the patient at some point during or prior to Step 10, when it becomes possible to determine that the results of stimulation are not acceptable such that repositioning is required.</p>
inserting a radiofrequency probe into the lumen of the needle such that the radiofrequency probe contacts a conductive portion of the needle at a distal end of the needle to thereby establish an	<p>As described in Step 7 of the Procedure, “insert the full length of the RF Probe/Temperature Sensor down the [lumen] of the [DTR device].” (Exhibit I at p. 5).</p> <p>7. Once the cannula is properly positioned carefully remove the stylet from the cannula and <u>insert the full length of the RF Probe/Temperature Sensor down the shaft of the Sterile Single Use Trident™ RF Insulated Cannula.</u></p>

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electrically conductive path from the radiofrequency probe to the filament; and	<p>As shown, the lumen [5] of the DTR device's needle is configured to and does accept the radiofrequency "RF" probe [7] therein.</p> <p>As described in the DTR IFU, "Current from the RF generator is applied to the patient through the uninsulated portion of the lesion electrode." (Exhibit I at p. 3). Thus, it would be understood that physical contact occurs between the uninsulated exterior surface of the RF probe [7] and the uninsulated interior surface of the lumen [5] within the circle [8] of the last photo to the right, and that this physical contact thereby establishes an electrically conductive path from the RF probe [7] to the filaments [6a-c].</p>

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<p>operating the radiofrequency probe, the tip, and the filament as a monopolar electrode, with radiofrequency energy from the radiofrequency probe being conducted to the filament through the electrically conductive path and transmitted by the filament.</p>	<p>* The second image above showing the RF probe [7] fully inserted into the lumen [5] of the needle depicts the related DTRH device. Upon information and belief, the needle of the DTRH device is substantively the same as the needle of DTR when it is combined with the required RF probe and thus the same features are present in the needle of the DTR.</p> <p>As described in Step 10 of the Procedure in the DTR IFU, “sensory and/or motor electrical stimulation” is applied to the patient. (Exhibit I at p. 5).</p> <p>As described in the Warnings and Precautions Section of the DTR IFU, the RF generator must be set in the “monopolar mode of operation.” (Exhibit I at p. 6). This instructs that the DTR device is intended to only be used as a monopolar electrode.</p> <p>As described in the DTR IFU, “Current from the RF generator is applied to the patient through the uninsulated portion of the lesion electrode.” (Exhibit I at p. 3). The current applied is radiofrequency energy, which is conducted from the RF probe [7] to the filaments [6a-c] such that the filaments [6a-</p> <p>10. Apply sensory and/or motor electrical stimulation as indicated by your protocol to verify correct electrode placement. If the results of stimulation are not acceptable and repositioning of the cannula is required, first fully withdraw the tines into the cannula and then reposition. Repeat electrical stimulation as indicated.</p> <p>WARNING AND PRECAUTIONS Inspect all components for damage prior to each use. If components are damaged in any manner they must not be used. Damaged components must be discarded or returned for evaluation/repair. Damaged components may result in patient or operator injury.</p> <ul style="list-style-type: none"> • Check if device is reading room temperature before placing it into a patient • Do not start treatment without verification of correct placement • Do not start treatment if device doesn't read body temperature and impedance <p>...</p>

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	c] transmit the current to the patient.	<ul style="list-style-type: none">• Application of RF energy may cause undesirable neuromuscular stimulation.• During power delivery, the patient should not be allowed to come in contact with ground metal surfaces.• Set RF generator in monopolar mode of operation <p>4. <i>Return Path Electrodes</i></p> <p><u>RECOMMENDATIONS FOR RETURN PATH (GROUND, REFERENCE) ELECTRODES</u></p> <p>The return path (also termed ground, reference, indifferent, neutral or dispersive electrode) electrode serves to complete the current path through the patient. Current from the RF generator is applied to the patient through the uninsulated portion of the lesion electrode. It must find a return path back to the RF lesion electrode.</p>